

Office Action Summary

Application No.

10/562,142

Applicant(s)

BAR ET AL.

Examiner

Rita Desai

Art Unit

1625

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-11, 13, 14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 9-11, 14, 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 13 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 08/16/2010
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Applicant's request for reconsideration of the finality of the rejection of the Office Action of 17 February 2010 is persuasive and, therefore, the finality of that action is withdrawn. That action is presented below as a non-final action.

DETAILED ACTION

Claims 1-7, 9-11, 13, 14, 16-21 are in the application.

Claims 9-11, 14, 17-21 are withdrawn.

Claims under consideration are 1-7, 13, and 16.

Response to the arguments:-

Regarding the 103 rejection over WO 03/014116 Bauser et al. WO 03051877 Zhang et al, and WO 0248144 Niewohner et al. in view of GB1153670, US 4694085, Liebig's Ann. Chem 9, 1534-1544 1981. (caplus english abstract DN 95:203671 .)

applicants argue that they have amended the claims to have R5 to be an alkyl.

Applicants have provided some data with unexpected results. That the compounds with an alkyl at the R5 position. have a better activity.

The examiner does not find this convincing first of all because the prior art does have similar antitumor activity . Modifying the compounds by substituting a H for a CH3 or an alkyl is prima-facie obvious as a person skilled in the art of drug design would be motivated to make minor modifications with the expectation that the compounds would still have the same properties. The rejection is therefore maintained. KSR v Teleflex 2007.

” 82 USPQ2d at 1396. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. See MPEP § 2143 for a discussion of the rationales listed above along with examples illustrating how the cited rationales may be used to support a finding of obviousness. See also MPEP § 2144- §2144.09 for additional guidance regarding support for obviousness determinations.

In this case the rational falls within the “Obvious to try with a finite number of identified , predictable solutions with a reasonable expectation of success.”

The reasoning for the rejection over Casagrande et al and Anderson et al is also the same.

The rejection of the claims under 35 USC 112 has been withdrawn as applicants have amended the claims.

New matter

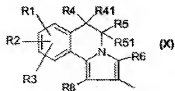
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The definition of R2 has been changed to include hydrogen.

This was not presented originally nor is it in the definition given in the specifications . R2 could never have been hydrogen.



In which

- R1 is halogen, nitro, 1-4C-alkyl, 1-4C-alkoxy, 1-4C-alkoxy-2-4C-alkoxy, 3-7C-cycloalkoxy or 3-7C-cycloalkylmethoxy,
R2 is 1-4C-alkoxy or halogen,
R3 is hydrogen or 1-4C-alkoxy,

On page 6 another subset is described

A subspect (subspect a1) of the special aspect a according to this invention worthy to be mentioned is the use of a structure-element of the formula X,

in which

- R1 is halogen, nitro, 1-4C-alkyl, 1-4C-alkoxy, 1-4C-alkoxy-2-4C-alkoxy, 3-7C-cycloalkoxy or 3-7C-cycloalkylmethoxy,
R2 is 1-4C-alkoxy or halogen,
R3 is hydrogen or 1-4C-alkoxy,
R4 is hydrogen,

It should be noted that both R2 and R3 are not H.

In some embodiments R2 is aH and R3 an alkyl or an alkoxy such as on page 7.

A subaspect (subaspect s2) of the special aspect A according to this invention more worthy to be mentioned is the use of a structure-element of the formula X,

in which

R1 is halogen or 1-4C-alkoxy,

R2 is hydrogen, halogen or 1-4C-alkoxy,

R3 is 1-4C-alkoxy,

R4 is hydrogen,

R41 is hydrogen,

R5 is hydrogen, methyl or ethyl,

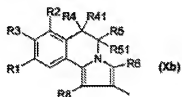
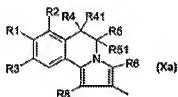
R51 is hydrogen,

R6 is methyl, ethyl or methoxycarbonylethyl,

R8 is cyano,

as integral part of the overall structure of compounds which inhibit PDE10.

A subaspect (subaspect s3) of the special aspect A according to this invention in particular worthy to be mentioned is the use of a structure-element of the formula Xa or Xb



in which

as a first alternative,

R1 is chlorine or fluorine,

R2 is hydrogen,

R3 is methoxy or ethoxy,

R1 is methoxy or ethoxy,

R2 is hydrogen,

R3 is methoxy or ethoxy,

There are several such subsets given in the spec. Even though some places R2 is a H, the scope that R2 and R3 both are not hydrogen. Thus between R1, R2 and R3 the ring always has to have atleast 2 substituents.

By amending claim 1 to read R2 is a H, the scope of claim 1 changes and introduces new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite “ which inhibits PDE10, comprising a structural element as an integral part of the compound's overall structure, wherein said structure-element has the formula X according to claim 1, “

Is vague and indefinite as it is unclear what else is included in the compounds. the term “comprises” is open and can include other features not in the claim.

The claims are different than those in 10/562137, 11794497, as their R7 is a phenyl instead of the methyl group in the applicants compounds.

Conclusion

No claim is allowed.

Any inquiry concerning this communication should be directed to Janet L. Andres whose telephone number is (571)272-0867. The examiner can normally be reached on Monday - Friday, 8:00-5:30.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625

/Rita J. Desai/
Primary Examiner, Art Unit 1625

February 5, 2010.
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